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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,640	07/11/2001	Avi Ashkenazi	10466/85	3104

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/903,640	ASHKENAZI ET AL.
	Examiner Konstantina Katcheves	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 39-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 39-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 39-51 are pending in the instant application.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Page 147 of the specification contains embedded hyperlinks. Applicant is required to delete any and all embedded hyperlinks and/or other forms of browser-executable code. The attempt to incorporate subject matter into the patent application by reference in this manner is considered to be an improper incorporation by reference. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 39-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 39-51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claimed invention is drawn to isolated polypeptide of SEQ ID NO:263, which is referred to as PRO343 throughout the specification.

The specification discloses the sequencing of a polypeptide, which displayed some homology with proteases. On page 29, line 35 of the specification, Applicant discusses PRO343 in generalities stating that this protein has homology with proteases. Applicant has described neither the proteases that PRO343 is homologous to nor what degree of homology is found. The specification, as filed, does not provide any evidence or guidance suggesting the claimed protein's activity is involved in any particular activity or disease state.

Although the specification generally asserts that proteases are useful in biological processes including protein digestion, activation, inactivation or modulation of peptide hormone activity *etc.* On page 138, lines 10-14, Applicant states that PRO343 may be used “both *in vivo* for therapeutic purposes and *in vitro*,” and that “those of ordinary skill in the art will well know how to employ the . . .PRO343 polypeptides of the present invention for such purposes.” Contrary to Applicant’s assertion, without a specific asserted or well-established utility not even one of extraordinary skill in the art would be able to use the PRO343 polypeptide. Applicant fails to disclose any use for the specific protein PRO343, nor any fragments and homologues thereof. No evidence or guidance is provided that would suggest to a skilled artisan that there is any utility in using protein sequence since Applicant has not adequately describe any specific activity for the alleged protein. Applicant’s references to PRO343 in the specification are few. Example 41 on page 180, only discloses the isolation of the full-length cDNA clone of PRO343. Table 9 on pages 230-234 only disclose a gene amplification assay wherein PRO343 expression is increased in some tumor cell lines. The mere over expression of a protein without some knowledge as to its function or use would provide neither a specific nor well-established utility.

Thereby, it is doubtful whether the protein of PRO343 can be used in any of Applicant's asserted utilities.

Additionally, the specification's lack of a specific and substantial asserted utility or a well established utility is further supported by the specification which notes that a search of the proteins encoded by the claimed sequences merely revealed similarity to proteases in general. See page 29. The accurate prediction of the claimed protein activity cannot be based on primary structure alone. Berendsen (Science Vol.282 1998) teaches that "folding to the stable native state has not yet occurred and the simulations do not contain any relevant statistics on the process." See page 643, second column. Further supporting Berendsen's teaching of inability to predict activity based on homology, Galperin et al. (Nature Biotechnology Vol.18 2000) teach that "sequence comparison methods, even the best ones, are of little help when a protein has no homologs in current databases or when all database hits are to uncharacterized gene products." Galperin et al. also disclose that "assessing the actual power of the context based method for protein function prediction requires extensive testing by labor-consuming, case-by-case, computational, and eventually experimental analysis." Attwood (Science Vol.290 2000) also states that it is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences." It is clear from the above references that one could not possibly predict the function of a protein from structure alone. Moreover, given a mere assertion of homology to proteases and the lack of even basic homology data, Applicant could not possibly have an appreciation for the function of PRO343. Thus, Applicant has failed to establish a specific utility.

Therefore, as discussed above, neither the art nor the specification as filed provides a specific and substantial asserted utility or a well established utility for the claimed nucleotides or amino acid sequences; thereby, casting doubt on the utility of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention . . . [emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Applicant's claims are drawn to sequences with 80%, 85%, 90%, 95% and 99% homology to SEQ ID NO:263. Claims 39-49, 50 and 50 are further drawn to limitations comprising the extracellular domain of SEQ ID NO:263. These claims read on a broad genus of polypeptides. However, neither the claims nor the specification as filed indicate what distinguishing attributes the members of the claimed genus of polypeptides share. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claimed polypeptides, it is only required that a polypeptide maintain a certain degree of homology to the claimed polypeptide sequences or comprise an undefined extracellular domain.

Thus, the scope of the claims includes numerous structural variants, and the genus is highly varied because a significant number of structural differences between the genus members are permitted, and neither the specification or the claims provide any guidance as to what specific changes could be made. Furthermore, there are no common functional attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is varied, the disclosed sequence alone is not sufficient to describe the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
September 14, 2002


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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